

What is claimed is:

1. An assay device comprising:

a housing;

a first device region formed by or within said housing for receiving a fluid sample; and
a second device region fluidly connected to said first device region, said second device region comprising one or more capture zones on a surface within said housing, each said capture zone comprising molecules of a first receptor reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of said analyte of interest with molecules of said first receptor and produce a measurable signal in response;

wherein said assay device is configured and arranged to deliver a predetermined volume of said fluid sample from said first device region to said second device region for determining the presence or amount of one or more analytes of interest therein.

2. An assay device according to claim 1, wherein the molecules of said first receptor is an antibody or a binding fragment thereof.

3. An assay device according to claim 1, further comprising one or more reagents disposed in the device for mixing with said predetermined volume of said fluid sample to form a reaction mixture when said predetermined volume is delivered from said first device region to said second device region.

4. An assay device according to claim 3, wherein said one or more reagents comprise one or more labeled reagent species, wherein molecules of each said labeled reagent species comprise an enzyme conjugated to a second receptor reactive with said analyte of interest, wherein molecules of said labeled reagent species form sandwich complexes with molecules of said analyte of interest and with molecules of said first receptor.

5. An assay device according to claim 1, wherein said first receptor is bound to one or more latex particles, and said latex particles are bound to said capture zone.

6. An assay device according to claim 1, comprising a plurality of capture zones corresponding to a plurality of different analytes of interest.
7. An assay device according to claim 1, wherein said predetermined volume of said fluid sample is delivered from said first device region to said second device region by capillary action.
8. An assay device according to claim 1, wherein said analyte sensor uses amperometric measurements to detect said electrochemical signal.
9. An assay device according to claim 1, wherein said analyte sensor uses potentiometric measurements to detect said electrochemical signal.
10. An assay device according to claim 1, wherein said surface within said housing comprising capture zones is an inner surface of the housing.
11. An assay device comprising:
 - a housing;
 - a first device region formed by or within said housing for receiving a fluid sample;
 - a second device region fluidly connected to said first device region, said second device region comprising one or more capture zones on a surface within said housing, each said capture zone comprising molecules of a first antibody or binding fragment thereof reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of said analyte of interest with molecules of said first antibody or binding fragment thereof and produce a measurable signal in response; and
 - a labeled reagent species dissolvably disposed on a surface within said housing that is in fluid communication with said second device region, wherein molecules of said labeled reagent species comprise an enzyme conjugated to a second antibody or binding fragment thereof reactive with said analyte of interest, wherein molecules of said labeled reagent species form sandwich complexes with molecules of said analyte of interest and with molecules of said first antibody or binding fragment thereof.

12. An assay device according to claim 11, wherein said first antibody or binding fragment thereof is bound to one or more latex particles, and said particles are bound to said capture zone.
13. An assay device according to claim 11, comprising a plurality of capture zones corresponding to a plurality of different analytes of interest.
14. An assay device according to claim 11, wherein a predetermined volume of said fluid sample is delivered from said first device region to said second device region by capillary action.
15. An assay device according to claim 11, wherein said analyte sensor uses amperometric measurements to detect said electrochemical signal.
16. An assay device according to claim 11, wherein said analyte sensor uses potentiometric measurements to detect said electrochemical signal.
17. An assay device according to claim 11, wherein said surface within said housing comprising capture zones is an inner surface of the housing.
18. A method for detecting an analyte of interest in a fluid sample, comprising:
 - introducing said fluid sample into a device comprising:
 - a housing;
 - a first device region formed by or within said housing for receiving a fluid sample; and
 - a second device region fluidly connected to said first device region, said second device region comprising a capture zone on a surface within said housing, said capture zone comprising molecules of a first receptor reactive with said analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of analyte with molecules of said first receptor and produce a measurable signal in response;
 - delivering a volume of said fluid sample from said first device region to said second device region, wherein molecules of said analyte present in said volume react with molecules of said first receptor at said capture zone;

contacting said analyte of interest with molecules of a labeled reagent species, wherein said labeled reagent species comprises an enzyme conjugated to a second receptor reactive with said analyte of interest, wherein molecules of said labeled reagent species form sandwich complexes with molecules of said analyte of interest and with molecules of said first receptor at said capture zone;

contacting said sandwich complexes with molecules of a substrate for said enzyme; and measuring a signal produced by said analyte sensor.

19. A method according to claim 18, wherein one or both of said first and second receptors are antibodies or fragments thereof.

20. A method according to claim 18, wherein said labeled reagent species is disposed in the device for mixing with said volume to form a reaction mixture when said volume is delivered from said first device region to said second device region.

21. A method according to claim 18, wherein said first receptor is bound to one or more latex particles, and said particles are bound to said capture zone.

22. An assay device according to claim 18, wherein said volume of said fluid sample is delivered from said first device region to said second device region by capillary action.

23. A method according to claim 18, wherein said analyte sensor uses amperometric measurements to detect said electrochemical signal.

24. A method according to claim 18, wherein said analyte sensor uses potentiometric measurements to detect said electrochemical signal.